

BEST AVAILABLE COPY

1211739

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

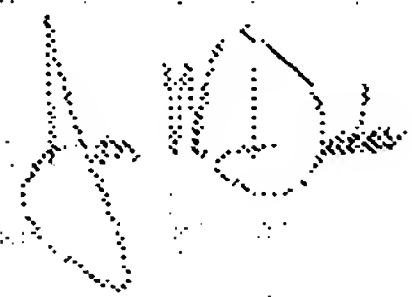
United States Patent and Trademark Office

August 13, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 60/503,709
FILING DATE: *September 17, 2003*

Certified by



Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office



17236 U.S. PTO
09/17/03

Please type a plus sign (+) inside this box →



PTO/SB/16 (02-01)
Approved for use through 10/31/2002. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No. EV340034093US

INVENTOR(S)					
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)			
Eric L.	MEIJER	Best, THE NETHERLANDS			
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
REPEATED EXAMINATION REPORTING					
CORRESPONDENCE ADDRESS					
Direct all correspondence to:					
<input type="checkbox"/> Customer Number		<input type="text"/>		→ <div>Place Customer Number Bar Code Label here</div>	
OR Type Customer Number here					
<input checked="" type="checkbox"/> Firm or Individual Name	THOMAS E KOCOVSKY, JR				
Address	FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP				
Address	1100 SUPERIOR AVENUE, SEVENTH FLOOR				
City	CLEVELAND	State	OH	ZIP	44114
Country	US	Telephone	216/861-5582	Fax	216/241-1666
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		13		<input type="checkbox"/> CD(s), Number <input type="text"/>	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		3		<input type="checkbox"/> Other (specify) <input type="text"/>	
<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:				06-0308	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.				FILING FEE AMOUNT (\$) 160	
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,
SIGNATURE

Date 09/17/2003

TYPED or PRINTED NAME THOMAS E. KOCOVSKY, JR.

REGISTRATION NO. 28,383
(if appropriate)

TELEPHONE 216 861-5582

Docket Number: PHUS030320USP

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

17302 U.S. PTO
60/503709
09/17/03

REPEATED EXAMINATION REPORTING

Background of the Invention

The present invention relates to disease or physical condition analysis and reporting. It finds particular application in conjunction with monitoring disease or physical progression over time and will be described with particular reference thereto. It is to be appreciated, however, that the present invention is applicable to cross patient studies, and other applications as well.

There is a long standing interest in tracking the progression of disease and physical conditions of patients. When a patient is initially diagnosed, the speed with which a condition is progressing affects a prescribed treatment regimen. After a patient receives a regimen of treatment, follow-up visits ascertain the quality and effectiveness of the prescribed treatment, whether other courses of action are in order, and the like. A significant portion of this patient tracking and continued diagnosis occurs in the realm of diagnostic imaging. A patient with symptoms is diagnosed or a diagnosis is confirmed using an imaging procedure.

Today, a patient's medical records are typically maintained in a computer database. The record includes previous diagnostic images, although the prior images are often of differing regions of the body and were generated with imaging parameters and in imaging modalities geared for other types of examinations. Nonetheless, the diagnosing physician can page through the images in the patient's file manually to look for images that include the same region and might provide insights into the development of the problem. Further, after or during the treatment, the patient may return for further imaging to assess the success of the treatment. The physician can retrieve prior images at various stages in the treatment and display them, side by side with the current image. The physician can visually compare the latest image with the previous image or previous images with each other. The progression of the images aids the physician in making a determination about the rate of progress of the malady and success of the treatment.

Currently, the images to be compared are displayed concurrently in separate windows on a computer monitor, or similar display device. This can be cumbersome, and the progression of the region of interest can be intuitively difficult to follow. Additionally, the images often were taken at different time intervals and have a different scale, perspective, contrast, and other image properties. For instance, two images of an irregularly shaped brain tumor taken from different angles may show the tumor as being different sizes. In such a scenario, it would be difficult to tell whether the tumor actually changed in size, or if one viewed image was taken through a slice in which a direction in which the tumor is wider.

Although imaging sequences and scans can be saved and reproduced, it is difficult to accurately reproduce the physical position of a patient within a scanner on different days. Slightly different patient positions from scan to scan will result in slightly different image perspectives, given the exact same imaging scan or sequence.

More factors are introduced if a physician attempts to do a cross-modality comparison. For instance, the patient with the brain tumor may have a current MRI and an older CT scan that includes the region. Different modalities emphasize different tissue properties and may show the tumor with different degrees of differentiation relative to the surrounding tissue.

The present application contemplates a new and improved object identification system, which overcomes the above-referenced problems and others.

Summary of the Invention

In accordance with one aspect of the present invention, a diagnostic image processing system is provided. A parameter extraction processor extracts selected parameter values from a diagnostic image representation or from data for generating the diagnostic image. A subject database stores the image representation and the extracted parameter values in association with at least a patient identity and a date. The database is updated each time the subject is imaged. A report formatting means formats the extracted parameter values from a plurality of diagnostic images generated at different times into a report.

In accordance with another aspect of the present invention, a method of diagnostic image processing is provided. A diagnostic image representation is displayed and a region of interest is selected on the display. Parameter values from the selected region are extracted. The image representation
5 along with the extracted parameter values are stored in a database in association with at least a subject identity and a date. The extracted parameter values from a plurality of diagnostic images are formatted into a report.

One advantage of the present invention resides in improved patient progress tracking.

10 Another advantage resides in improved patient diagnosis and treatment planning.

Another advantage resides in a more intuitively meaningful image display.

15 Another advantage results in easier cross-modality scan comparison.

Another advantage resides in easier scan result comparison.

Still further advantages and benefits of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

20

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are
25 not to be construed as limiting the invention.

FIGURE 1 is a diagrammatic illustration of an imaging system with repeated examination capabilities;

FIGURE 2 is a flow diagram illustrating the construction of a repeated examination report; and,

30 FIGURE 3 is an exemplary report format including a graphical representation of a progression vs. time.

Detailed Description of the Preferred Embodiments

With reference to FIGURE 1, a variety of diagnostic imagers are connected with a hospital database 10. Preferably, the diagnostic imagers include a high field magnetic resonance (MR) scanner 12, a low field MR scanner 14, a CT scanner 16, a nuclear camera 18, and a digital x-ray system 20. Other diagnostic imaging equipment is also contemplated. Each diagnostic imager includes or is associated with a reconstruction processor for implementing reconstruction algorithms for the corresponding modality. Typically, selected reconstructed images are saved into the patient's record in the hospital database 10 rather than the underlying data although either or both can be. The images, preferably volume images, are stored with an electronic indication of the imaged region.

Looking to the high field magnetic resonance scanner 12 by way of example, the data from the scanner is reconstructed by a reconstruction processor 30 and stored into an image memory 32. A video processor 34 withdraws selected portions of the reconstructed image for display on a video or other human readable monitor 36. The other scanners include similar reconstruction processors, image memories, video processors, and displays.

Using a mouse 40 or other suitable pointing and drawing means, the operator outlines the region of interest on a displayed image or otherwise indicates the region of interest. Taking the monitoring of a tumor, by way of example, a processor or means 42 isolates the designated tumor from the surrounding tissue. This may be done by comparing gray scale or other properties of the designated tumor relative to the surrounding tissue in the diagnostic image memory. The generated isolated image of the tumor of interest is stored in a memory 44 which is examined by a parameter extraction processor or means 46 that extracts parameters of the isolated tumor such as its volume, average density, blood flow rate to or through it, diffusion coefficients, fractional diffusion anisotropy values, spectroscopic values, metabolic information, and the like. The extracted parameters are preferably stored with the image data in the patient database 10 to facilitate the comparison of these parameters with similar parameters derived from earlier or later images.

To monitor the progress of the tumor, the operator initiates a program 50 which searches the hospital database 10 for other images of the same patient which include the region surrounding the tumor. Images of the region of the patient which include the tumor are analyzed 52 to isolate the tissue which is at
5 the same location as the tumor.

Once the corresponding portion of the archived images has been located, a reformatting means 54 reformats the images to convert the images to the same viewing direction such as with a multi-planar reformatting technique which re-grids the images and scales the reformatted images as the present examination
10 images. The reformatted images of the same region of interest are then provided to the video processor 34 for display on the monitor 36. The isolating means 42 is then used manually or automatically to isolate the tissue at the same location as the tumor with similar grayscale, MR number, or other similar characteristic. Preferably, the isolating means goes to the same location and tries to isolate a
15 tumor with the same physical properties. The automatic isolating means may or may not be successful. For example, some of the images may have been taken before there was a tumor. Others may have been taken in a modality in which the tumor is hard to distinguish. Also, the tumor may have grown eccentrically. That is, in early images, the tumor could have been displaced from the current center of
20 mass and the program may be missing it. The diagnosing physician uses the cursor 40 to outline regions of potential interest on each of the archived images for isolation and analysis.

Some of the retrieved archived images may have been stored with a coordinate shift relative to the current diagnostic image. In one embodiment, the
25 operator manually designates a corresponding point in each image and a reformatting means 54 shifts the images to align the common points. In another embodiment, a pattern comparing means 56 compares the images of generally similar regions of the subject by isolating common landmark points, the pattern means 56 determines a transform which translates the images into registration.

30 Once the prior images have been retrieved and the corresponding regions registered and the tumor or other tissue of interest isolated, the parameters extracted by the parameter extraction means 46 are sent to a report formatting

processor or means 60. The report formatting means 60 includes a plurality of report generation options. The extracted values are ordered by the data compilation processor 60 and placed into a repeated examination report, that is, they are placed in an intuitive visual format, preferably according to date. Charts, tables, graphs and other comparable display formats are suitable for presenting the extracted values. For example, in a patient who has a brain tumor, one of the likely extracted values would be size of the tumor. A chart that shows the size of the brain tumor as a function of time would be one exemplary mode of display. Not all values will be available in every imaging modality. Preferably, dates corresponding to data points with no data are omitted from the presentation of that value. More specifically, a table option 62 generates a table which sets forth corresponding parameters of interest from each of the preceding images. For example, the table could set forth the volume of the tumor in each image, the date of the image, etc. in tabular format. A graphing means or algorithm 64 presents a selected parameter of the tumor, such as volume or tissue density, and plots the change in that parameter versus time. Because the prior images have probably not been taken at regular periodic images, the graphing processor includes a means 66 for scaling the time between exams to make the timeline of the graphs linear, logarithmic, or the like.

Of course, for retrieved images that were stored after treatment commenced, the parameter extraction means may simply extract the measured parameters which were stored with the images.

Over time, patients may be imaged repeatedly, with multiple image modalities. With reference to FIGURE 2, the process for incorporating further scans of the patient into the patient database 10 is illustrated. Before beginning a patient's treatment, an initial scan of the patient is performed 70. An image is reconstructed and displayed for the user 72. The user then selects a region of interest of the image 74. Preferably, the region includes a portion of a static body structure, to aid in future image registrations. After the region of interest is selected, selected image parameters are then withdrawn from the image 76. The hospital database 10 is searched 78 for prior images of the same region of the subject. These archived images are reformatted and scaled 80. The same regions

of each image are analyzed, either automatically or manually, and the selected parameters are extracted 82. The extracted parameters are stored 84 in the patient database 10. Once the parameters have been extracted and stored, they need not be extracted again. Of course, if new extraction techniques are developed, the
5 extraction process can be repeated. The extracted parameters are formatted 86 into a report format such as a table or a graph as illustrated in FIGURE 3. The reports are used by the physician to confirm a diagnosis, plan treatment, and the like.

After the scan, the patient receives the prescribed therapy, e.g. chemotherapy or oncological radiation therapy. Alternately, the "treatment" may
10 simply be the passage of time, such as allowing a broken bone to mend. In either case, periods of time lapses between diagnostic image sessions, to allow the region to respond to the administered treatment, whether it is active or passive. After sufficient time has elapsed, a new scan of the region of interest is performed 90. If the same scan is desired, a sequence controller 91 accesses the patient database 10
15 to retrieve the sequence used to generate the baseline image and recreates that sequence. Alternately, a different sequence may be used, generating different geometries or resolutions, or a different modality entirely may be used. In either instance, downstream software identifies 92 the corresponding region of interest in a subsequent image. Parameters are extracted 94 from the new raw data set and
20 image and are, in turn, stored 84 in the patient database 10 according to patient ID and date. If different parameters are extracted, the prior images are retrieved from the patient database 10 and the new parameters are extracted from them. After each imaging session the report and the database 10 are updated to chart the progression of the region of interest over time.

25 In another display embodiment, with reference again to FIGURE 1, when a set of images and corresponding data values are selected for viewing, the registration processor 54 reformats and registers the retrieved images to the baseline image. Preferably, the image is translated, rotated, and uniformly scaled to bring it into alignment with the original image. Once all images are registered,
30 they are displayed to the user in an intuitive format. For example, all the images in order by time are displayed on the user interface 36 concurrently. In another example, a cinè processor 100 processes the images for display in a cinè mode,

showing an action progression of the region of interest over time. To supplement the cinè mode, an extrapolator 102 compares the images, and their dates, and extrapolate intermediate sub-images between the actual images as needed to generate all the image frames for a cinè display with a linear or other selected
5 timeline. The extrapolator 102 creates images based on a real time scale (e.g. one frame per week) to aid in visual intuitiveness.

The invention has been described with reference to the preferred embodiments. Modifications and alterations will occur to others upon a reading and understanding of the preceding detailed description. It is intended that the
10 invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS:

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A diagnostic image processing system comprising:
 - a parameter extraction processor (46) for extracting selected parameter values from a diagnostic image representation or from data for generating the diagnostic image;
 - a subject database (10) that stores the image representation and the extracted parameter values in association with at least a patient identity and a date, the database being updated each time the subject is imaged; and,
 - a report formatting means (60) for formatting the extracted parameter values from a plurality of diagnostic images generated at different times into a report.
2. The system as set forth in claim 1, further including:
 - a user interface (36) with which a user selects a region of interest of at least a baseline one of the diagnostic images from which the parameter values are to be extracted.
3. The system as set forth in claim 2, wherein the parameter extraction processor (46) extracts the values from the selected region of interest.
4. The system as set forth in claim 3, further including:
 - an image registration processor (54) that aligns and scales the diagnostic images.
5. The system as set forth in claim 2, further including:
 - a database searching means (50) for searching the subject database (10) for other diagnostic images of the selected region of interest of the subject, the

parameter extraction processor (46) extracting the selected parameter values from the other diagnostic images of the selected region.

6. The system as set forth in claim 5, wherein the report formatting means (60) includes a graphing means (64) for plotting change of a selected parameter versus time.

7. The system as set forth in claim 5, further including a cinè image sequence generating means (100) for converting the selected region of interest of the diagnostic images into a temporally scaled sequence of cinè images.

8. A method of diagnostic image processing comprising:
displaying a diagnostic image representation;
selecting a region of interest on the display;
extracting selected parameter values from the selected region;
storing the image representation along with the extracted parameter values in association with at least a subject identity and a date in a database (10);
formatting the extracted parameter values from a plurality of diagnostic images into a report.

9. The method as set forth in claim 8, further including:
generating image representations including the region of interest of the subject at different dates; and,
storing the generated image representations in the subject database (10) catalogued by at least subject identity and date.

10. The method as set forth in claim 8, further including:
searching the subject database (10) for additional diagnostic images of the selected region of interest.

11. The method as set forth in claim 10, further including:

registering diagnostic images retrieved from the database with the selected region of interest.

12. The method as set forth in claim 11, further including:
displaying the diagnostic images sequentially by date.

13. The method as set forth in claim 12, further including:
interpolating the diagnostic images such that the sequentially displayed images are displayed with a linear time scale.

14. The method as set forth in claim 11, further including:
extracting the selected parameter values from the plurality of diagnostic images.

15. The method as set forth in claim 14, wherein the formatting step includes:
presenting the selected parameter values in tabular format by date.

16. The method as set forth in claim 15, wherein the formatting step includes:
presenting the selected parameter values in a graph versus time with a pre-selected time scale.

17. The method as set forth in claim 14, wherein the parameter values include at least one of:
a volume of the selected region;
a blood flow through the selected region;
an average density in the selected region;
diffusion coefficients of the selected region;
fractional diffusion anisotropy values in the selected region; and,
spectroscopic peak intensities in the selected region.

18. A method of diagnostic imaging comprising:
creating an image representation of a portion of a subject;
selecting a region of the image representation for further study;
storing the image representation in a subject database cataloged by
at least a subject identity and a date of scan;
extracting selected parameter values from the image representation
and storing them in the subject database;
creating at least one other image representation of the portion of the
subject on a subsequent date;
storing the at least one other image representation and other
additional values of interest in the subject database;
spatially registering the image representation and the at least one
other image representation;
displaying the image representations to show a time progression of
the region.

19. The method as set forth in claim 18, further including:
presenting the selected parameter values in one of graphical and
tabular form showing a progression of the parameter values over time.

20. The method as set forth in claim 18, wherein the image
representation and the at least one other image representation are produced by
different modalities of diagnostic imaging and registered by aligning structures
identifiable in all modalities involved, and further including:
enhancing the resolution of the image representations by utilizing
complementary characteristics of the modalities involved.

REPEATED EXAMINATION REPORTING

Abstract

A plurality of diagnostic images of a region of interest of a subject are generated and stored in a patient database (10). In one of the images, a region of interest, such as a tumor, is identified. The database is searched for the other images of the same region of interest. Parameter values indicative of characteristics of the tumor are extracted from each image and displayed in tabular or graphic format by time. The images are reformatted, scaled, and displayed in a cinè format to illustrate a temporal evolution of the tumor in the region of interest.

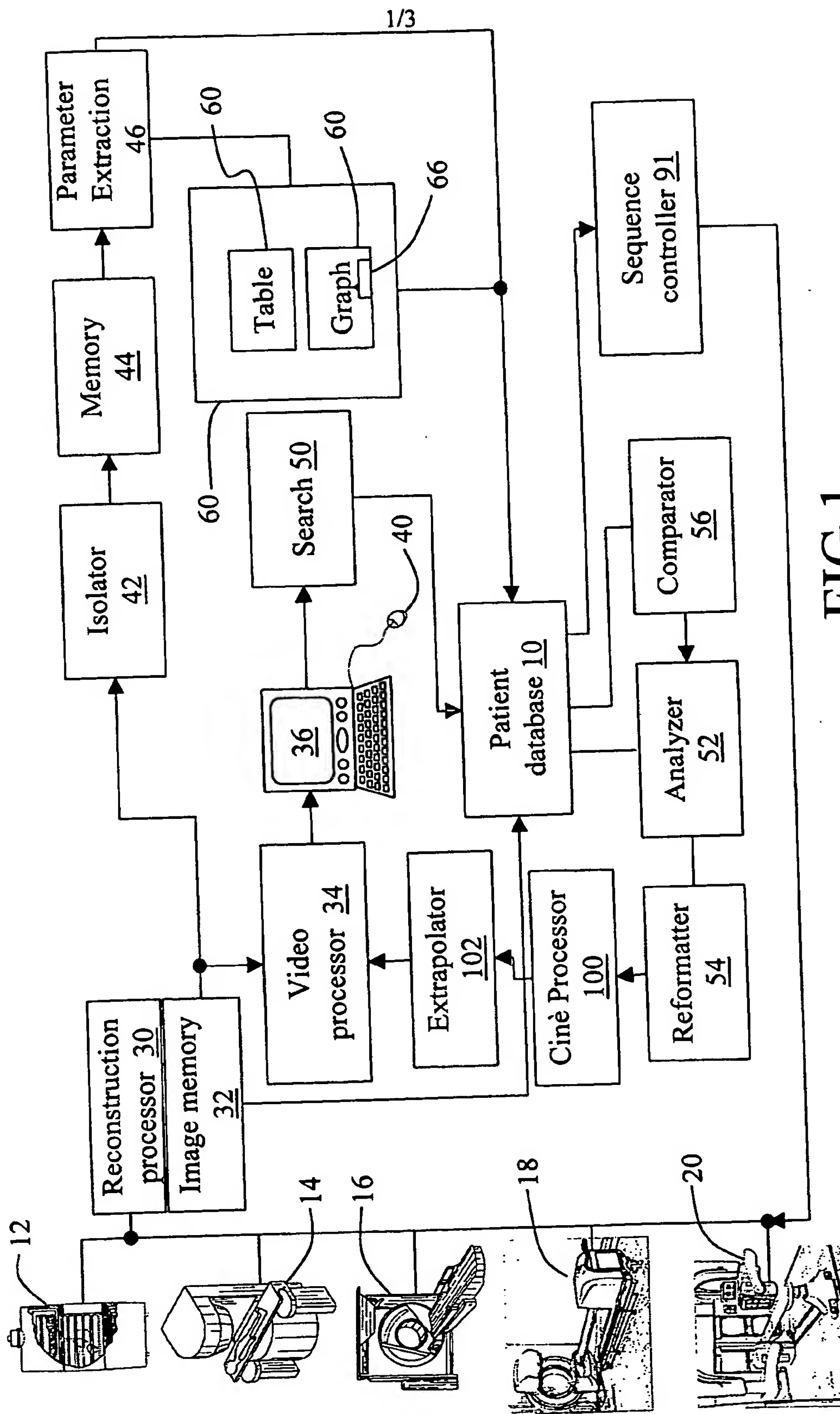


FIG.1

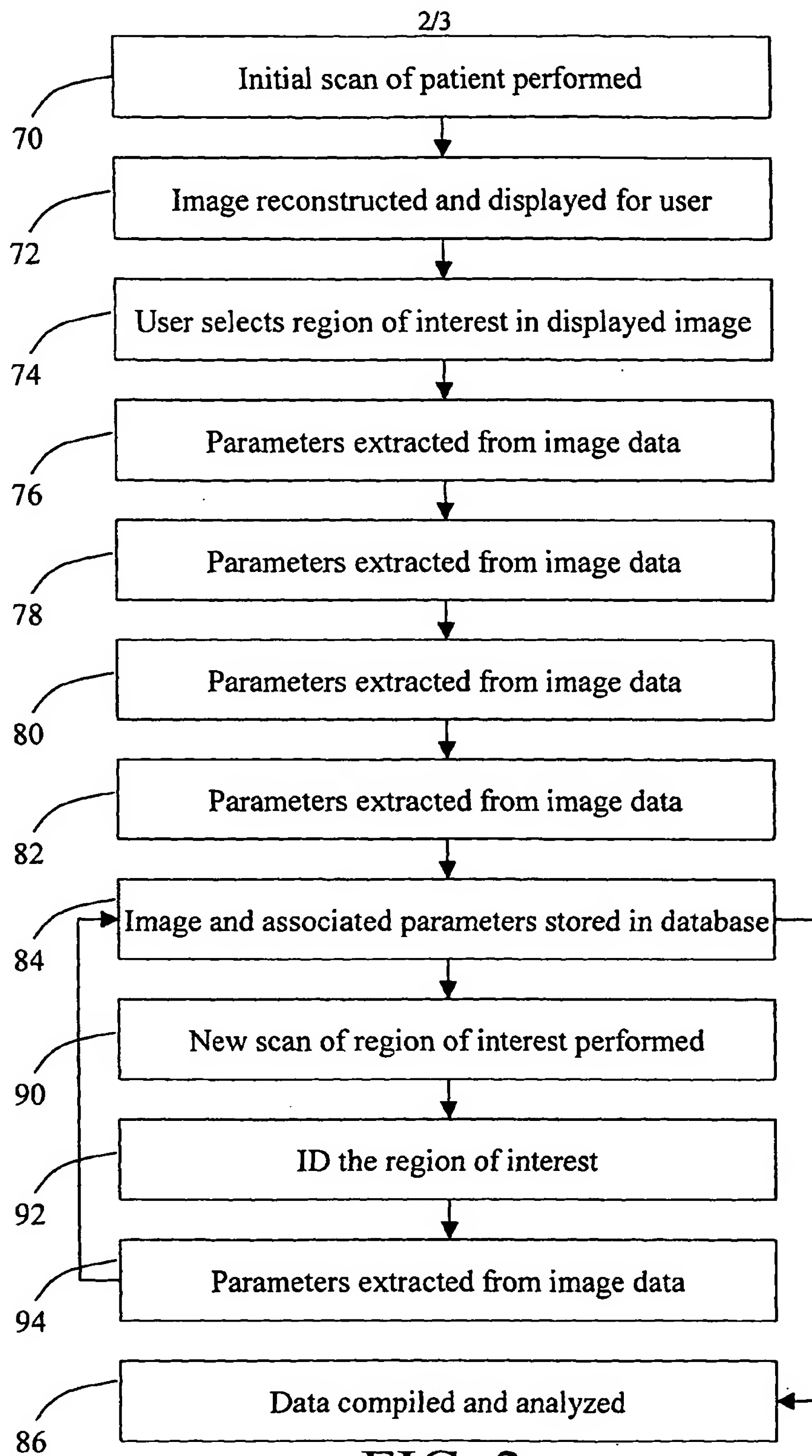
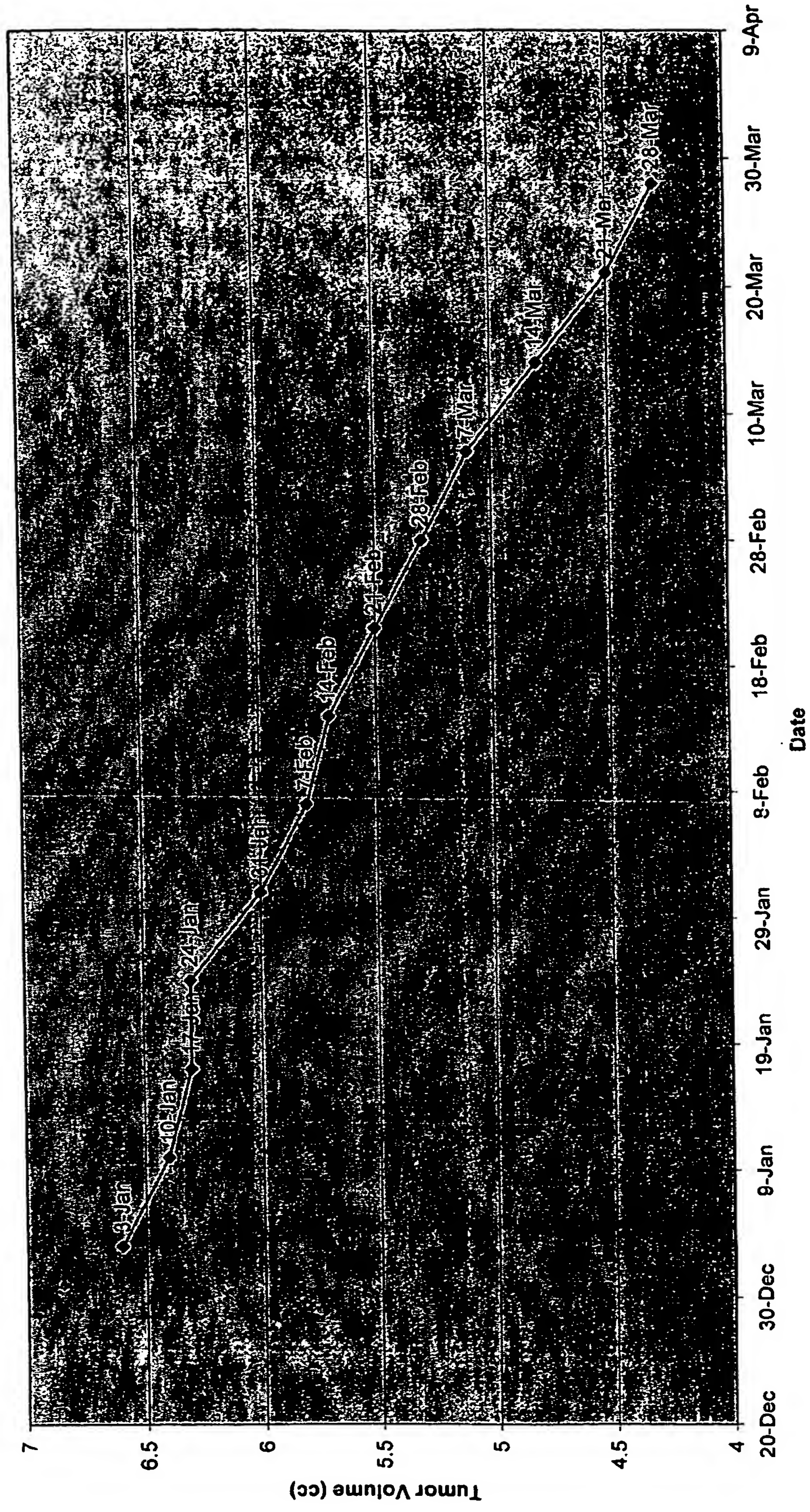


FIG. 2

FIG. 3



APPLICATION DATA SHEET

Mail Stop: Provisional Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Inventor Information

Inventor One Given Name:: Eric L.
Family Name:: MEIJER
City:: Best
Country:: NL

Correspondence Information

Name Line One:: Thomas E. Kocovsky, Esq.
Name Line Two:: FAY, SHARPE, FAGAN,
Name Line Three:: MINNICH & McKEE, LLP
Address Line One:: 1100 Superior Avenue, Seventh Floor
City:: Cleveland
State or Province:: OH
Postal or Zip Code:: 44114-2518
Telephone One:: (216) 861-5582
Fax:: (216) 241-1666
Electronic Mail:: TKocovsky@faysharpe.com

Representative Information

Registration Number:: 28,383

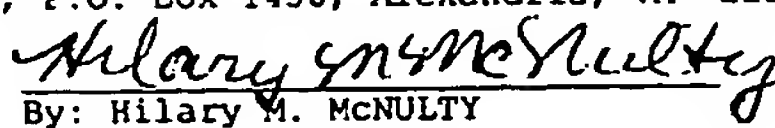
Application Information

Title Line One:: REPEATED EXAMINATION REPORTING
Total Drawing Sheets:: 3
Application Type:: Provisional
Docket Number:: PHUS030320USP (613162)

"Express Mail" Mailing Label Number EV340034093US

Date of Deposit: SEPTEMBER 17, 2003

I hereby certify that this paper or fee is being deposited
with the United States Postal Service "Express Mail
Post Office to Addressee" service under 37 C.F.R. 1.10 on the
date indicated above and is addressed to: Provisional Patent Application,
Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


By: Hilary M. McNULTY

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IB04/051665

International filing date: 01 September 2004 (01.09.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/503,709
Filing date: 17 September 2003 (17.09.2003)

Date of receipt at the International Bureau: 20 September 2004 (20.09.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.